

**EXHIBIT 48**

**to**

**Declaration of Kenneth A. Gallo in  
Support of Defendant's Motion for  
Reconsideration or, in the Alternative, for  
Certification of an Interlocutory Appeal**

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL ROBOT ) Lead Case No.:  
ANTITRUST LITIGATION ) 3:21-cv-03825-VC

THIS DOCUMENT RELATES TO:  
ALL CASES

SURGICAL INSTRUMENT SERVICE ) Case No.:  
COMPANY, INC., ) 3:21-cv-03496-VC

Plaintiff,

vs.

INTUITIVE SURGICAL, INC.,

Defendant.

VIDEO-RECORDED VIRTUAL REMOTE DEPOSITION OF  
DAVID FABRICANT

Scottsdale, Arizona  
November 8, 2022  
10:20 a.m. MST

REPORTED BY:  
Janice Gonzales, RPR, CRR  
AZ Certified Court  
Reporter No. 50844

1 the commercialization to take an additional year?

2 A. We would have found something out that  
3 had a delay in the product being available for sale  
4 and something -- one of the reasons that would cause  
5 it -- of that -- of that delay would be the -- would  
6 be the 510(k) regulatory requirement.

7 Q. Okay. Would it also be the other  
8 potential risks that are listed here on the bottom of  
9 page 2?

10 A. Those -- those are potential delays to  
11 revenue.

12 Q. Okay. But also -- so when you say -- is  
13 that different than the question I'm asking you, I  
14 guess? I want to understand your answer.

15 A. There's time to market and then there's  
16 the slope of the revenue. So the first question is  
17 when can you get first sale. The second is how  
18 quickly are you able to generate sales.

19 Q. You're saying the regulatory issue was  
20 time to market issue?

21 A. Yes.

22 Q. Okay. And that for the other potential  
23 risks here are all just revenue risks, which are  
24 different than time to market?

25 A. So the 510(k), without it you can't sell

1 it, so that's time to market. Unwillingness of  
2 hospitals. That's the amount of time it would take  
3 to get a hospital to do a contract with us relative  
4 to the investigation of their existing contracts. We  
5 can't do that activity with the hospital until the  
6 510(k) is clear. So we can't engage the hospital,  
7 but that would affect the -- that steepness that I  
8 was saying of the revenue growth. The next one of  
9 Intuitive's reaction is only going to affect the  
10 steepness of the revenue growth. Additional cost for  
11 R&D remediations. R&D remediations, that would most  
12 likely prevent us from being able to sell the device.  
13 So that goes with the first one of -- until  
14 remediations and the Rebotix product is at the  
15 Stryker quality standard, Stryker would not be able  
16 to do the promotions or the sales process. So that's  
17 time to market, not the steepness of the slope. And  
18 then the pricing pressures are just -- would go with  
19 the steepness of the slope of the revenue.

20 Q. Okay. So with regard to revenue risk due  
21 to potential reaction of Intuitive -- do you see that  
22 line?

23 A. Yes.

24 Q. Okay. You see "legal"? It just says,  
25 "i.e., legal." Do you see that line? It's not a

1 Q. And what is the date of that exhibit, if  
2 it's in front of you?

3 A. It is October 19, 2015.

4 Q. And what does that exhibit tell you about  
5 what they told you at the time in terms of whether  
6 Rebotix had or had not sought FDA clearance?

7 THE WITNESS: John, are you pulling that  
8 up or no?

9 MR. DOMINGUEZ: Yeah, I'm on it. I'm on  
10 it, yeah.

11 THE WITNESS: I didn't know if you were  
12 going to share it.

13 MR. DOMINGUEZ: I thought you want me to  
14 do that hot key control thing, sure. You want me to  
15 show it.

16 THE WITNESS: Right below the last bullet  
17 point, that paragraph.

18 MR. DOMINGUEZ: Where it says "Raptor  
19 submitted"?

20 THE WITNESS: Yes.

21 To answer your question, Raptor did  
22 submit their 510(k). The FDA had not cleared a  
23 remanufacturer -- a reprocessor for a 510(k), and  
24 they were issued a deficiency letter that they needed  
25 to utilize the rate framework, forcing these devices

1 for reprocessing. Therefore, the company had  
2 indicated that they lack a fundamental understanding  
3 of SDD regulatory framework and then had requested to  
4 leverage Sustainability Solutions expertise to  
5 facilitate the 510(k) clearance.

6 BY MR. RUBY:

7 Q. And in what way did they propose to  
8 leverage Stryker's regulatory expertise to get  
9 Rebotix closer to 510(k) clearance?

10 A. That was the other document that was  
11 referenced, that said that they were at  
12 roughly 30 percent to Stryker's standard for being  
13 able to go back to the FDA with a response. So they  
14 were looking to leverage at Stryker's R&D for testing  
15 and regulatory for FDA engagement, and that's why the  
16 timeline got pushed out and that's why the cost was  
17 shown. The original and then the subsequent -- the  
18 updated was the incremental. I think we showed in  
19 the exhibit 1.5 million.

20 Q. Okay. At the time of your first sequence  
21 of contacts with Rebotix, what business model did  
22 they say that they intended to pursue once they had  
23 regulatory clearance?

24 A. I don't understand what that means.

25 Q. Did they talk to you that what they

1 wanted to do was open up a store and sell EndoWrists?  
2 Did they want to send a technician to places of  
3 business and repair EndoWrists if they needed it?  
4 Were they proposing to buy -- in some fashion, buy  
5 and sell EndoWrists for the purpose of -- EndoWrists  
6 for the purpose of replacing the usage indicator?  
7 That's what I mean by the business model. At a high  
8 level, what kind of business did they say they wanted  
9 to be in?

10 MR. DOMINGUEZ: Objection to form.  
11 Misstates the evidence.

12 Go ahead.

13 THE WITNESS: They were going to interact  
14 directly with the hospitals to have the used devices  
15 shipped to them. They would -- they would issue a  
16 repair that was not 510(k) and sent back to the  
17 hospital at a discount.

18 BY MR. RUBY:

19 Q. And did they tell you what this repair  
20 would consist of?

21 A. Yes.

22 Q. What was that?

23 A. There were several components. One was  
24 to reset the counter, another was to re-tension the  
25 cable. The third was to ensure the functionality of

1 the distal tip, and the fourth was to resharpen any  
2 cutting distal ends. There may have been others, but  
3 that's the high level that I recall.

4 Q. In the first sequence of contacts, did  
5 Mr. Papit and/or Mr. Mixner tell you that Rebotix  
6 didn't really need 510(k) clearance for the kind of  
7 repair service that they wanted to offer?

8 A. Yes, that's -- that was the difference  
9 between Rebotix being -- going as a repair company  
10 and Stryker being a reprocessing company that  
11 required a 510(k).

12 Q. I don't understand what you just told me.  
13 What does that mean?

14 A. Rebotix is part of another company,  
15 Benjamin Biomedical, that Mr. Mixner owned. That was  
16 a repair company. Rebotix provided repair  
17 EndoWrists, which was the four, five things I just  
18 mentioned, but as a repair device, it did not require  
19 a 510(k) from the FDA. Stryker's quality system and  
20 regulatory counsel would not let Stryker go forward  
21 with this device unless it received a 510(k) from the  
22 FDA.

23 Q. Did you ever explain to Mr. Mixner and/or  
24 Mr. Papit why it was that Stryker was not interested  
25 in going ahead with them unless 510 clearance was



1           obtained?

2                   A.     Yes.

3                   Q.     What did you say to them?

4                   A.     I don't recall other -- I don't recall  
5           other than our -- we will not go forward unless this  
6           is a FDA-cleared device.

7                   Q.     Well, did you explain to them whether or  
8           not Stryker believed that it was legal to go forward  
9           with the business they had in mind without FDA  
10          clearance?

11                  A.     That, I don't recall, if we gave them any  
12          advice on how they wanted to operate Rebotix.

13                  Q.     Did you ever discuss with Rebotix, with  
14          Mr. Mixner, and/or Mr. Papit what kind of structure  
15          there might be to a financial transaction between  
16          Stryker and Rebotix if Stryker decided to go ahead  
17          with that?

18                  A.     Yes.

19                  Q.     And what did you say to them about that?  
20          What did you tell them?

21                  A.     It's the LOI terms -- or IOI terms.

22                  Q.     And do you recall in -- approximately  
23          what those were?

24                         THE WITNESS:   John, if you can pull up  
25          document -- or Exhibit 239b, as in boy, and it's the

1       tried to explain to us that they didn't think it was  
2       required under the -- under a repair service.

3       BY MR. RUBY:

4               Q.     I'm sorry for talking over you. I'll try  
5       to slow down.

6               After they explained to you they thought  
7       that 510(k) clearance wasn't required because this  
8       was a repair, did you after that explain to them,  
9       well -- I'm para- -- these are my words. Did you  
10      explain to them, Well, that's your opinion, but  
11      there's not going to be a deal with Stryker unless  
12      510 clearance was obtained, or words to that effect?

13              A.     One of the key considerations for -- for  
14      Stryker was the 510(k) clearance.

15              Q.     And you told them that?

16              A.     Yes.

17              Q.     Did you ever tell Mr. Papit and/or  
18      Mr. Mixner about any opinion that you personally had  
19      as to whether the -- what they described as a repair  
20      required 510(k) clearance or not?

21              A.     That, I don't recall, if I gave them my  
22      opinion.

23              Q.     Did you ever tell them whether or not you  
24      agreed with their opinion, that what they were  
25      describing as a repair required 510(k) clearance?